UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

In re: MEDTRONIC, INC., IMPLANTABLE DEFIBRILLATORS PRODUCTS LIABILITY LITIGATION

Multidistrict Litigation No. 05-1726 (JMR/AJB)

This Document Relates to: All Cases

MEDTRONIC, INC.'S MEMORANDUM IN SUPPORT OF MOTION TO DISMISS THE MASTER CONSOLIDATED COMPLAINT FOR INDIVIDUALS

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I. Introduction and Summary of Argument.

Defendant Medtronic Inc. ("Medtronic") hereby moves under Rules 12(b)(6) and Rule 9(b) to dismiss Plaintiffs' Master Consolidated Complaint for Individuals ("Master Complaint") in its entirety.

A. Introduction.

This is a product liability action where Plaintiffs do not even allege the life-saving devices at issue have ever actually malfunctioned or failed to perform exactly as designed. Plaintiffs' claims are a lamentable response to Medtronic's field action advising of a remote risk of premature battery depletion in certain Medtronic defibrillators. Plaintiffs now seek to concoct a lucrative mass tort -- in the absence of mass injuries -- indeed, in the absence of any injury at all. Plaintiffs' effort to create a claim where none exists is without legal merit. The Master Complaint should be dismissed.

B. Summary of Argument.

To survive a motion to dismiss, a product liability plaintiff must allege his injuries were caused by *actual product malfunction* -- not the "chance" the product may fail at some unspecified time in the future. This is true under Minnesota law, Eighth Circuit law, and the decisions of every other state and federal court to consider the issue. *See, e.g., Briehl v. Gen. Motors Corp.*, 172 F.3d 623, 628 (8th Cir. 1999) (upholding dismissal of all of plaintiffs' product liability claims):

> Since the Plaintiffs failed to allege that any defect had actually manifested itself in their vehicles, the Plaintiffs' allegations of damages failed to meet the pleading requirements for defective products.

Id; see also O'Brien v. Medtronic, Inc., 439 N.W. 2d 151, 154 (Wis. Ct. App. 1989) ("Extending liability where an individual pacemaker is properly functioning merely because other units of the same model have failed, without more, is not in society's best interest.") Here, Plaintiffs have not alleged -- because they cannot -- that their "injuries" are due to any malfunction of the Medtronic defibrillators at issue (the "Marquis Devices").[1] Thus, Plaintiffs cannot state a claim -- under any state law -- because they cannot properly plead a Device

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[1] Because Plaintiffs' Master Complaint uses differing and internally inconsistent terms to describe the Marquis Devices, *see infra* Part IV(B)(3), Medtronic will refer to the defibrillators at issue in this litigation as the "Marquis Devices" or "Devices." This definition *DOES NOT* include two defibrillator models Plaintiffs attempt to include in this litigation that had a completely different potential failure mechanism, contained different batteries from the Marquis Devices, and were not subject to the February 2005 Field Action. Medtronic has filed a motion to strike references to these two devices -- the Micro Jewel II Model 7223 Cx ("Micro Jewel II") and Gem DR Model 7271 ("Gem DR") -- as being outside the scope of this MDL. *See* Medtronic, Inc.'s Motion to Strike, for Partial Dismissal and for Severance of Certain Claims, filed February 20, 2006 (the "Motion to Strike").

Thus, the terms "Marquis Devices" or "Devices" refer ONLY to the defibrillators that were subject to the February 2005 Field Action -- i.e., the Devices that contained Chi4420L batteries manufactured between April 2001 and December 2003. *See* Master Complaint at ¶ 68 (listing, incorrectly in some instances, seven of the eight Marquis Devices subject to the Field Action as the only Devices containing the Chi4420L battery: Marquis VR Model 7230, Marquis DR Model 7274, Maximo VR Model 7232, Maximo DR Model 7278, InSync Marquis Model 7277, InSync II Marquis Model 7289, and InSync III Marquis Model 7279).

malfunction or defect. As this requisite pleading element is missing from Plaintiffs' Master Complaint, their claims should be dismissed in their entirety.

Plaintiffs' Master Complaint is also internally inconsistent and at times simply incomprehensible. Plaintiffs group the Devices at issue into three separate and defined categories. They then proceed to use these three defined terms interchangeably throughout the Master Complaint. Reading from the Master Complaint, it is impossible to determine which devices Plaintiffs refer to regarding which claims.

Perhaps this confusion is intended to mask the seminal flaw of the Master Complaint -- in not one instance do Plaintiffs allege they were injured as a direct and proximate result of the malfunction of a Marquis Device. The only hint of a connection between physical injury and Device malfunction is as follows:

> The *possibility* of Device malfunction led Plaintiffs to replace their Devices, and during replacement, there was a *possibility* that "complications" would arise.

Master Complaint at ¶ 108 (emphasis added). In addition to failing to allege actual Device malfunction, Plaintiffs do not allege any replacement "complications." Thus, at the end of the day, Plaintiffs are only able to allege the hypothetical "possibilities" of injuries arising from Device replacement complications. Under basic concepts of Article III standing and product liability

law, Plaintiffs' utter failure to move out of the realm of the hypothetical and plead actual injury caused by actual Device malfunction dooms their claims.

Plaintiffs' individual claims fail for other reasons. For example, Plaintiffs attempt to assert claims for fraud under Minnesota statutory law, yet this Court has explicitly held product liability claims will not lie under these statutes because they do not advance the "public interest" -- especially where (as here) the alleged "defective" product is no longer on the market.

Plaintiffs also claim breach of warranty, yet seek non-economic damages unavailable under a warranty theory, and the only "contracts" mentioned are "promotional statements" and "product literature" directed towards hospitals and physicians, rather than Plaintiffs (who are not actual purchasers of the Devices). Since none of Plaintiffs' claims can survive as a matter of law, Medtronic respectfully requests dismissal of the Master Complaint in its entirety.

II. Background Facts.

For purposes of this Motion, the facts alleged by Plaintiffs are presumed to be true. *See* Fed. R. Civ. P. 12(b). Although this Motion is predicated on purely legal grounds, the relevant background as set forth in the Master Complaint and materials referenced therein are summarized below.

A. Medtronic devices at issue in this litigation.

Medtronic is one of the world's pioneering medical technology companies. Medtronic designs, manufactures, and sells a wide range of implantable medical

devices, including implantable defibrillators. *See* Master Complaint at ¶ 25. The devices in this litigation are certain implantable cardioverter defibrillators ("ICDs") and cardiac resynchronization therapy defibrillators ("CRT-Ds") with batteries manufactured between April 2001 and December 2003. *See* Master Complaint at ¶¶ 58-59.

The Marquis Devices are complex medical devices used to treat life-threatening heart rhythm disturbances that can lead to sudden cardiac arrest. Of these Devices, four are ICD's, and four are CRT-D's. *See* Master Complaint at ¶¶ 58-59.

The Devices contain a small computer, a battery, and a capacitor. The capacitor stores an electric charge from the battery and, during defibrillator therapy, releases it all at once, thereby allowing a relatively small battery to deliver a large electric charge. Some Device models deliver an electrical charge to shock the heart into a normal rhythm if there is a rapid, life-threatening rhythm in the lower chambers of the heart. *See* Master Complaint at ¶¶ 29-37.

The CRT-D's[2] deliver electric impulses to coordinate the pumping of the heart's two lower chambers to improve heart failure symptoms as well as

[2] One of the CRT-Ds, the InSync III Protect Model 7285, was never sold commercially or used clinically in the United States and is also a subject of Medtronic's Motion to Strike.

defibrillation (when needed) to correct dangerous heart rhythms. *See* Master Complaint at ¶ 37.

B. History leading up to February 2005 Field Action.

In early 2003, Medtronic first identified a potential premature battery depletion issue during routine testing of machinery being qualified to add manufacturing capacity. *See* Master Complaint at ¶ 71. At the time of this discovery, all Marquis Devices in patients and in the field were performing as expected and within all performance parameters.

By late 2003, Medtronic had developed a replacement battery that eliminated the potential battery shorting mechanism. *See* February 2005 letter to physicians ("Advisory").[3] On October 23, 2003, the FDA approved a pre-market approval ("PMA") supplement for the Marquis Devices with the newly designed battery. *See* Master Complaint at ¶ 87. Throughout 2003, there still were no field returns or any confirmed injuries associated with the potential battery issue. *See generally* Master Complaint. The FDA's approval did not revoke or otherwise suspend the original PMA approval for Marquis Devices or bar Medtronic from distributing the Marquis Devices. Despite authority to do so, the FDA did not

[3] The full-text of the Advisory is attached to the Affidavit of Lori Cohen ("Cohen Aff.") as Exhibit A. Because Plaintiffs' Master Complaint is expressly based on the Field Action, *see* Master Complaint at ¶¶ 58-59, the Court may consider the text of the Advisory. *See, e.g., Moses Com. Sec., Inc. v. Comprehensive Software Sys., Inc.*, 406 F.3d 1052, 1063 n.3 (8th Cir. 2005).

order Medtronic to stop selling Devices with the original battery design. *See* 21 U.S.C. § 360(e) (authorizing the FDA to revoke PMA approval); 21 CFR § 814.47 (authorizing the FDA to suspend PMA approval); 21 CFR § 814.46(e) (authorizing the FDA to withdraw PMA approval).

In April 2004, Medtronic received a single report from the field of what appeared to be the premature battery depletion issue described above. *See* Master Complaint at ¶ 90. Although there were no reported injuries caused by premature battery depletion in the field, by December 2004, Medtronic received eight additional field returns of Devices. *See* Master Complaint at ¶ 91.

This observed failure rate -- 9 units out of 87,000 implanted -- was still well-within expected reliability for the Devices. Even so, Medtronic prudently instituted the Field Action because "highly accelerated bench testing indicate[d] that the rate of this shorting mechanism . . . may increase to between 0.2 percent and 1.5 percent over the second half of device life." *See* Advisory.

Thus, while the *maximum possible failure rate* for a Marquis Device was 1.5% -- and only during the second half of that Device's life -- Medtronic nevertheless voluntarily instituted the Field Action in February 2005.

C. February 2005 Field Action.

On February 10, 2005, Medtronic voluntarily began alerting physicians with patients implanted with Marquis Devices potentially subject to the battery depletion issue. *See* Advisory. In its communications to physicians, Medtronic

recommended patient management options to address the potential battery issue. *See* Cohen Aff., Ex. A and ¶3. Medtronic's Advisory announced the following:

- Medtronic was advising physicians about a potential "battery short mechanism" in the Marquis Devices "having batteries manufactured prior to December 2003";
- Medtronic had identified nine out of 87,000 implanted devices (approximately 1 in 10,000 or 0.01%) that exhibited this shorting mechanism;
- Based on "highly accelerated bench testing" the current rate [0.01%] may "increase to between 0.2% and 1.5% over the second half of device life;" and
- "There have been no reported patient injuries or deaths due to this issue. . . . [and] batteries produced after December 2003 are not effected. Specific battery design changes were implemented in December 2003 that eliminate the possibility of this internal shorting mechanism."

D. Management Options Communicated to Physicians.

The options Medtronic offered to physicians included: continuing to monitor their Device patients every three months; informing their patients of symptoms that should prompt them to seek follow-up care; and programming the alert on the Device to "On-High," which alerts patients to low batteries. In

addition, Medtronic offered to supply a small magnet patients could place over their Device daily, causing the Device to emit a tone if functional, to ensure proper battery operation. Medtronic also offered to provide a replacement device at no cost to patients who decided, in consultation with their physicians, to have their Device replaced, as well as $2,500 in unreimbursed medical expenses. For patients choosing not to have their Device explanted, Medtronic offered up to $1,000 of unreimbursed medical expenses for additional monitoring.

In July 2005, Medtronic provided physicians with updated device performance information, as well as further detailed information about various treatment options and information with which to respond to questions from patients.[4]

Based upon the Field Action, Plaintiffs now assert claims against Medtronic.

E. Two Types of Collective Plaintiffs.

Plaintiffs in these consolidated actions fall into two distinct groups: those who had their Devices explanted, and those who did not.[5] Neither group can claim the crucial element necessary to survive this Motion to Dismiss. No Plaintiff

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[4] The July 2005 update on Marquis Devices is attached as Exhibit B to the Cohen Aff.

[5] The claims of a third group of Plaintiffs -- the "TPP" Plaintiffs -- are addressed in Medtronic's "Motion to Dismiss the Third Party Payor Master Consolidated Master Complaint," filed concurrently with this Motion.

alleges an injury caused by a Device that malfunctioned or failed in any way. *See generally* Master Complaint. As such, their claims fail as a matter of law and should be dismissed.

III. Standard of Review.

In deciding a motion to dismiss, the Court assumes all facts in the complaint to be true and construes all reasonable inferences in the light most favorable to plaintiff. *See, e.g., Morton v. Becker*, 793 F.2d 185, 187 (8th Cir. 1986). But this does not mean the Court should blindly accept Plaintiffs' legal conclusions or unwarranted factual inferences. *See, e.g., Farm Credit Servs. of Am. v. Am. State* Bank, 339 F.3d 764, 767 (8th Cir. 2003) (noting the Court may "ignore legal conclusions, unsupported [factual] conclusions, unwarranted inferences, and sweeping legal conclusions cast in the form of factual allegations.") Indeed, the Court should grant a 12(b)(6) motion when "it is clear that no relief can be granted under any set of facts that could be proved consistent with the allegations in the complaint." *Alexander v. Peffer*, 993 F.2d 1348, 1349 (8th Cir. 1993) (quoting *Hishon v. King & Spaulding*, 467 U.S. 69, 73 (1984)).

Additionally, when deciding fraud-based claims, the Court should dismiss a plaintiff's complaint when the specific circumstances constituting the fraud are not "pled with particularity." Fed. R. Civ. P. 9(b). Rule 9(b)'s "specific" pleading requirements apply to all averments of fraud to ensure that "a defendant [is able] to respond and to prepare a defense to charges of fraud." *Commercial Property*

Invs., Inc. v. Quality Inns Int'l, Inc., 61 F.3d 639, 644 (8th Cir. 1995). "Conclusory allegations that a defendant's conduct was fraudulent and deceptive are not sufficient to satisfy the rule." *Tuttle v. Lorillard Tobacco Co.*, 2001 WL 821831 *2 (D. Minn. 2001).

IV. General Arguments (applying to all or more than one of Plaintiffs' causes of action).

A. Because *no Plaintiff* can allege injury due to an actual Marquis Device malfunction, *all Plaintiffs* lack Article III standing to assert their claims and lack the ability to meet the necessary elements of product liability claims.

1. Plaintiffs have not pled injuries (or a "significant likelihood of injuries") caused by a Device malfunction or defect -- because they cannot -- and therefore they lack Article III standing to maintain this lawsuit.

Plaintiffs vaguely claim they have suffered "injuries" and attempt to assert various common law or statutory claims under the laws of unspecified jurisdictions.[6] But because Plaintiffs cannot link their general "injuries" or "mental anguish" to actual Device failure or malfunction, they cannot maintain their claims. *See, e.g.,* Master Complaint at ¶ 109. Simply put, absent a demonstrated *likelihood* of injury resulting from malfunction of their Device, Plaintiffs -- under well-established Supreme Court and Eighth Circuit precedent --

[6] Given the Master Complaint does not identify any individual Plaintiff or the jurisdiction where any Plaintiff was implanted with a Marquis Device, Medtronic cannot address the myriad choice of law issues that would arise if this Complaint is allowed to go forward. *See, e.g., De Laventura v. Columbia Acorn Trust*, 2006 WL 235063 *8 (D. Mass. Feb. 1, 2006) ("MDL often gives rise to choice of law issues . . . .")

do not have Article III standing to maintain this lawsuit. *See, e.g., Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992) (noting that in order to have Article III standing, injuries must be "likely as opposed to merely speculative").

The Eighth Circuit has expressly adopted this "likelihood of injury" standard. As stated in *Shain v. Veneman*, 376 F.3d 815, 817 (8th Cir. 2004), "Although less specificity is required at the pleading stage than at the summary judgment stage . . . the Complaint must contain more than bald assertions of injury to survive a motion to dismiss." The Court pointedly expressed that when plaintiffs base their claims on a heightened risk of future harm, their claims only survive dismissal when the "increase in risk [is] sufficient to take the probability of harm out of the realm of the hypothetical and speculative." *Id.* at 818.

Here, Plaintiffs' claimed "injuries" are wholly hypothetical and speculative. ***Plaintiffs have not pled that any Device actually malfunctioned, and that this malfunction caused injury.*** In fact, in their general "Factual Allegations," Plaintiffs never allege that *any* of them actually suffered physical injury.[7]

None of Plaintiffs' causes of action specify any *actual injury* tied to any *actual malfunction* of any Device. For example, in Count One (Negligence), Plaintiffs allege "As a direct and proximate result of Defendant's conduct, Plaintiff

[7] The only reference to injury in the Factual Allegations is found in Paragraph 102, which apparently alleges the "injury" of a single female Plaintiff with a single undefined Device.

suffered and will continue to suffer [undefined] *personal injury* . . . ." Master Complaint at ¶ 109 (emphasis added).[8]

In fact, in the entire Master Complaint, the only guide Plaintiffs offer regarding what constitutes their "injuries" is one allegation that "replacement of the defective devices requires surgery that *can* result in complications that *may* cause damage to the patient's heart and other injuries to the patient." *Id.* at ¶ 108. But Plaintiffs do not allege *any* Plaintiff actually suffered such "complications" causing personal injury. They do not even allege these hypothetical complications are likely – only that they are *possible*.

Plaintiffs' claims of "possible" personal injury are legally insufficient to support a tort claim. Like all batteries, Device batteries have a limited life span, and therefore replacement is inevitable. Without a physical injury caused by an actual Device malfunction, Plaintiffs' Master Complaint boils down to this: some

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[8] Plaintiffs' other claims similarly fail to allege *any* defined injury caused by actual Device malfunction. Instead, *every* subsequent Count merely copies the same vague allegation of injury Plaintiffs allege in Count One -- an allegation referring to a single Plaintiff and referencing undefined "personal injury, economic loss, pecuniary loss, loss of companionship, and mental anguish . . . ." *Id.* at ¶ 117 (Count Two – Strict Liability); ¶ 122 (Count Three – Negligence Per Se); ¶ 128 (Count Four – Strict Liability); ¶ 134 (Count Five – Breach of Implied Warranty); ¶ 140 (Count Six – Breach of Express Warranty); ¶ 147 (Count Seven – Misrepresentation by Omission); ¶ 153 (Count Eight – Violation of Minnesota False Statement in Advertisement Act); ¶ 159 (Count Nine – Violation of the Minnesota Prevention of Consumer Fraud Act); ¶ 170 (Count Ten – Violation of the Minnesota Deceptive Trade Practices Act); ¶ 225 (Count Eleven – Violation of Consumer Protection Statutes).

Plaintiffs (those who chose to replace their Devices) underwent an inevitable replacement procedure somewhat sooner than they otherwise might have. Of course, whatever pain, discomfort or inconvenience these Plaintiffs experienced from "early" replacement is exactly what they would have experienced during a later "scheduled" replacement. There is no allegation that "early" replacement is somehow more painful or complicated than scheduled replacement. Likewise, there is no allegation that the costs associated with early replacement are greater than those incurred during "scheduled" replacements. Indeed, because Medtronic agreed to pay for the replacement device, the actual cost of early replacement is significantly less than it would be in a "scheduled" replacement. And even if any Plaintiff could somehow allege higher costs and, therefore, "economic loss" resulting from early replacement, such economic loss, in the absence of a physical injury, are not recoverable in tort. *See* Restatement (Third) of Torts, § 21(d), ("A product defect may render the product ineffective so that repair or *replacement* is necessary. Such a defect may result in consequential loss to the buyer...These losses are not recoverable"); *see also* Minn. Stat. § 604.10(a) (noting that "economic loss that arises from a sale of goods between parties who are each merchants in goods of the kind is not recoverable in tort").

Thus, as far as pleading the actual, *present* injury (or "sufficient likelihood" of future injury) required to maintain standing, Plaintiffs have failed completely.

See, e.g., Portis v. City of Chicago, 347 F. Supp. 2d 573, 576 (N.D. Ill. 2004) (dismissing claim for lack of standing because plaintiffs could not demonstrate "sufficient likelihood of future injury"); *see also generally* Master Complaint (failing to allege sufficient likelihood that Plaintiffs' Marquis Devices will cause future injury). Plaintiffs therefore do not have the "concrete and particularized" injury necessary to confer standing. *See, e.g., Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 180-81 (2000).

2. The Eighth Circuit, as well as Minnesota federal and state courts, have consistently held that product liability actions do not lie where -- as here -- "the alleged defect has not manifested itself in the [Plaintiffs' individual] product."

For the same reason Plaintiffs lack standing in the constitutional/Article III sense, they lack the ability to bring state-law claims -- claims all grounded in theories of product liability.

The Eighth Circuit addressed this very issue in *Briehl* and squarely held that the absence of an actual product malfunction is fatal to the plaintiffs' product liability claims:

> ***[W]here, as in this case, a product performs satisfactorily and never exhibits an alleged defect, no cause of action lies.*** Since the Plaintiffs have failed to allege any manifest defect and their vehicles perform in a satisfactory manner, the District Court was correct when it dismissed the Plaintiffs' Original Master Complaint.

Briehl, 172 F.3d at 628.

Briehl is instructive as it is factually similar to the present situation. There, plaintiffs brought a putative class action against General Motors ("GM") alleging a defective anti-lock braking mechanism in several vehicles. *Id.* at 625. They alleged -- as here -- that GM was aware of a defective mechanism, GM hid this information from the public, and GM promoted this mechanism as a highly effective safety device. *Id.* at 626; *see also* Master Complaint at ¶71 ("Medtronic was aware that the [battery] was at risk for sudden battery depletion resulting in internal shorting mechanism sometime during January 2003").

But just as Plaintiffs today cannot allege injury proximately caused by an actual Device malfunction, the *Briehl* plaintiffs could not allege they were injured due to the alleged anti-lock break defect. For this reason, the Eighth Circuit affirmed dismissal under Rule 12(b)(6). *See also LensCrafters, Inc. v. Vision World, Inc.*, 943 F. Supp. 1481, 2489 (D. Minn. 1996) (holding omission of factual allegations supporting link of product liability claim to compensable damages is fatal to claim); *Patton v. Newmar Corp.*, 538 N.W. 2d 116, 119 (Minn. 1995) (holding same regarding strict liability claim).

Thus, as in *Briehl*, Plaintiffs cannot maintain their claims because their bald allegations are "simply too speculative to allow [the] case to go forward." *Briehl*, 172 F.3d at 629.

3. *Other jurisdictions consistently hold similarly -- product liability claims must fail where the plaintiff cannot allege injury due to actual device malfunction.*

Courts around the country -- and especially in those jurisdictions represented in this multidistrict litigation -- have repeatedly and emphatically held that where a device does not malfunction, no product liability claims can attach to that device.[9]

For example, the *O'Brien*[10] court held Wisconsin law does not recognize a plaintiff's right to sue for product liability claims when those claims are solely based on a recall, and *not* on any device malfunction. "Had [plaintiffs] presented any evidence that [the] lead was defective or had malfunctioned, they would have a cause of action recognized under Wisconsin law . . . The mere fact that the model's failure rate was unusually high, as Medtronic admitted in its advisories, does not automatically create liability." *Id.* at 154. The court noted that allowing recovery absent actual device malfunction would lead to undesirable social outcomes:

> We do not want to impose liability on a company for making a particular unit that is not defective. . . . Because of the social utility of what companies like Medtronic do, *holding them liable for*

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[9] *See* Restatement (Third) of Torts, § 1 ("One engaged in the business of selling or otherwise distributing products who sells or distributes a defective product is subject to liability for harm to persons or property *caused by the defect.*") (emphasis added).

[10] 439 N.W. 2d 151 (Wis. Ct. App. 1989).

> *indirect or remote injuries is not warranted.* . . . Extending liability where an individual pacemaker is properly functioning merely because other units of the same model have failed, without more, is not in society's best interest.

Id.

Here, as discussed above, Plaintiffs can only vaguely allege "injuries." The fact that they cannot link those injuries to a Device malfunction means their claims are simply not recognizable under individually-applicable state laws. As one state supreme court noted, "many federal and state court decisions have affirmed the dismissal of claims brought under fraud, strict products liability, and other tort theories where the allegedly defective product has not actually malfunctioned." *Tietsworth v. Harley-Davidson, Inc.*, 677 N.W. 2d 233 (Wis. 2004) (examining "no injury" cases around the country, and calling these cases "too numerous to list").

A select few of these decisions are:

- *Pfizer v. Farsian,* 682 So. 2d 405, 407 (Ala. 1996) (holding plaintiff's belief that a product could fail in the future is not, without more, a legal injury sufficient to support plaintiff's claim).

- *Wallis v. Ford Motor Co.*, 2005 WL 1120218 (Ark. 2005) (dismissing claim where there was no allegation the defect had manifested itself).

- *Khan v. Shiley, Inc.*, 266 Cal. Rptr. 106, 110 (Cal. App. 1990) ("No matter which theory is utilized, where a plaintiff alleges that a product is defective, proof that the product has malfunctioned is essential to establish liability for an injury caused by the defect").

- *Zamora v. Shell Oil Co.*, 55 Cal. App. 3th 204, 208 (1997) (holding in the absence of a product malfunction, plaintiff cannot establish a defendant breached any duty).

- *Barbarin v. General Motors Corp.*, 1993 WL 765821 *2 (D.D.C. 1993) (dismissing claims of plaintiffs whose cars never malfunctioned).

- *Verb v. Motorola, Inc.*, 672 N.E. 2d 1287, 1295 (Ill. 1996) (dismissing claims against cellular telephone manufacturers alleging potential safety defects because "plaintiffs' future personal injury and damages claims constitute conjecture and speculation").

- *Willett v. Baxter Int'l, Inc.*, 929 F.2d 1094, 1097 (5th Cir. 1991) (precluding claims where plaintiffs "provided no evidence that their particular valves . . . were not performing as designed").

- *Jarman v. United Industries Corp.*, 98 F. Supp. 2d 757, 767 (S.D. Miss. 2000) (dismissing claims because no allegation that product *actually* malfunctioned).

- *Yost v. General Motors Corp.*, 651 F. Supp. 656, 657-58 (D.N.J. 1986) (holding complaint alleging design defect "likely to cause" damage failed to state a claim).

- *Martin v. Edwards Labs*, 457 N.E.2d 1150 (N.Y. 1983) ("An implanted or inserted device intended to perform a continuing function . . . causes no injury until the product malfunctions").

- *Weaver v. Chrysler Corp.*, 172 F.R.D. 96, 99-100 (S.D.N.Y. 1997) ("It is well established that purchasers of an allegedly defective product have no legally recognizable claim where the alleged defect has not manifested itself in the product they own").

- *Rall v. Medtronic, Inc.*, 1986 WL 22271 (D. Nev. Oct. 15, 1986) ("Plaintiff's contention that the mere presence of a polyurethane lead in the body, with or without any malfunction, establishes a basis for liability, and a question common to all members, defies reality").

- *Walus v. Pfizer, Inc.*, 812 F. Supp. 41, 44 (D.N.J. 1993) ("No provision in [New Jersey's product liability statue] authorizes a cause of action based on a claim that a normally functioning product might fail at some unknown time").

- *Keath v. Shiley, Inc.*, 1991 U.S. Dist. LEXIS 21872 *7 (N.D. Ohio 1991) ("A product is considered defective only if it causes an injury; it cannot be considered defective simply because it is capable of producing injury").

- *Kent v. Shiley, Inc.*, 1989 WL 88307 *2 (D. Or. 1989) (holding Oregon's product liability statute required product cause physical harm in order to subject manufacturer to liability).

- *Lauterbach v. Shiley, Inc.*, 1991 WL 148137 *9 (S.D. Tex 1991) ("There is no cause of action under Texas law where a plaintiff's product is and has been functioning without incident. Texas law does not recognize a claim seeking to recover for alleged concern or anxiety that a functioning product might fail at some future unknown time").

- *Martin v. Ford Motor Co.*, 914 F. Supp. 1449, 1453 (S.D. Tex. 1996) (stating that where plaintiffs admittedly have not sustained any personal injuries relating to seat belt restraint system, plaintiffs cannot succeed on their claims).

- *Murphy v. Shiley, Inc.*, 1991 U.S. App. LEXIS 17190 *1 (9th Cir. 1991) (holding Washington law does not allow recovery "absent product failure, malfunction, or product-caused accident").

As in all of the cases cited above and others, Plaintiffs' claims here are based on Devices that never actually malfunctioned. More importantly for purposes of this Motion, Plaintiffs fail even to *allege* that any of their Devices malfunctioned, let alone caused an injury tied to a malfunction.

B. Plaintiffs' common-law and statutory fraud claims -- Counts Seven through Eleven -- fail substantively and procedurally as Plaintiffs have failed to plead these claims with the requisite specificity.

The Eighth Circuit has held Rule 9(b)'s "specific" pleading requirements apply to all averments of fraud to ensure "a defendant [is able] to respond and to prepare a defense to charges of fraud." *Commercial Property Invs., Inc. v. Quality Inns Int'l, Inc.*, 61 F.3d 639, 644 (8th Cir. 1995). As this Court held, "[C]onclusory allegations that a defendant's conduct was fraudulent and deceptive are not sufficient to satisfy the rule." *Tuttle v. Lorillard Tobacco Co.*, 2001 WL 821831 *2 (D. Minn. 2001). Rather, in order to meet Rule 9(b)'s "heightened pleading requirement," Plaintiffs must set forth the "who, what, when, where, and how: the first paragraph of any newspaper story." *Id.* (citing *Parnes v. Gateway 2000, Inc.*, 122 F.3d 539, 549-50 (8th Cir. 1997)). All five of Plaintiffs' fraud-based claims, therefore, fail for lack of specificity.

Additionally, even if these claims had been pled with the requisite particularity, the fraud-based claims must be dismissed with regard to Medtronic's "CRT-D" devices, as by Plaintiffs' own defined terms, the fraud-based claims apply only to Medtronic's "ICD" devices. *See* Master Complaint at ¶¶ 58-59

1. Plaintiffs' common-law fraud claim (Count Seven -- Misrepresentation by Omission) is vague and lacks the specificity required under Rule 9(b).

Far from providing the "who, what, when, where, and how" to Medtronic's alleged fraudulent actions, Plaintiffs instead only provide a superficial recitation of the legal conclusion that "Defendant misrepresented the mechanical soundness and reliability of its ICD devices to the general public . . . ." *See Id.* at ¶ 142.

Although Plaintiffs make the standard boilerplate allegations that the "intentional misrepresentations and omissions were made willfully, wantonly or recklessly to Plaintiff," *Id.* at ¶ 145, they fail to allege specific facts to support such allegations. Their allegations, thus, fall substantially short of meeting the particularity standard of Rule 9(b). *See Parnes,* 122 F.3d at 550. Plaintiffs fail to identify any Medtronic representative who made representations to Plaintiffs or Plaintiffs' physicians. Similarly, there is no indication of where, when, or how these alleged misrepresentations were made. Most importantly, however, Plaintiffs have utterly failed to specify *what* specific statement(s) by Medtronic are allegedly fraudulent. Plaintiffs, therefore, fail to allege how any of these

unspecified statements affected them. Plaintiffs do not identify any specific representation, whether oral or written, as being false, much less how they were injured by their reliance on such unidentified misrepresentation. *See* Master Complaint at ¶¶ 141-47. Thus, Plaintiffs have failed to allege the "reliance" element essential to any fraud claim.

Finally, under Rule 9(b), Plaintiffs also are required to plead their fraud-based injuries with specificity. *See Parnes,* 122 F.3d at 550. As discussed above, Plaintiffs cannot tie any claimed injury to product malfunction, let alone an alleged misrepresentation regarding a malfunction that never manifested itself in Plaintiffs' Devices. Plaintiffs' Master Complaint leaves both the Court and Medtronic completely in the dark as to how Medtronic's "fraudulent" conduct could possibly have caused "injury," when, in fact, no Plaintiff was injured because of a Device malfunction.

Rule 9(b) flatly prohibits Plaintiffs' attempt at engaging the Court and Medtronic in a guessing game. *See, e.g., Tuttle*, 2001 WL 821831 at *2 ("[C]onclusory allegations that a defendant's conduct was fraudulent and deceptive are not sufficient to satisfy the rule.") Plaintiffs' vaguely pled fraud claims should be dismissed.

2. Plaintiffs' statutory/consumer fraud claims (Counts Eight-Eleven) similarly should be dismissed for lack of specificity under Rule 9(b).

Consumer fraud claims are subject to the same Rule 9(b) pleading requirements as common law claims. *See, e.g., Tuttle,* 2001 WL 821831 at *2 ("Notwithstanding the relative breadth of the consumer protection statutes, Rule 9(b) applies where, as here, the gravamen of the Master Complaint is fraud").

Here, Plaintiffs' consumer protection claims are undoubtedly grounded in fraud. *See, e.g.,* Master Complaint at ¶ 155 (alleging "Defendant intentionally concealed its design and/or manufacturing defect . . . ."). Thus, as with their common-law fraud claims, Plaintiffs have failed to provide Medtronic and the Court with the "who, what, when, where, and how" of the alleged consumer protection statutes violations. Medtronic, therefore, respectfully requests that Plaintiffs' fraud-based claims -- Counts Seven through Eleven -- be dismissed under Rule 9(b).

3. By their own terms, Plaintiffs' fraud-based claims only apply to Medtronic's "ICDs," and therefore these claims must be dismissed with regard to CRT-D devices.

Plaintiffs have limited their fraud-based claims to Medtronic's ICD's. This Court should take Plaintiffs at their word and refuse to consider fraud-based claims brought by Plaintiffs with CRT-D's.

Plaintiffs know the difference between the two types of devices. *Id.* at ¶ 5-6 (describing the difference between ICDs and CRT-D's); ¶ 58-59 (noting the February 2005 Field Action involved "four models of ICDs" and "four models of CRT-Ds"). In fact, Plaintiffs invented the term "Recalled Cardiac Devices" to refer collectively to these ICDs and CRT-Ds. *Id.* at 59 ("The Class I Recalled ICDs, Recalled ICDs, and the Recalled CRT-Ds are collectively referred to as the 'Recalled Cardiac Devices'").

Regarding Counts Seven through Ten, Plaintiffs only refer to Medtronic's "ICD devices." *Id.* at ¶ 142 (Count Seven); ¶ 149 (Count Eight); ¶ 156 (Count Nine); and ¶ 162 (Count Ten). Thus, even assuming their fraud based claims as to ICDs survive Rule 9(b), Plaintiffs cannot maintain these causes of action regarding CRT-Ds.

V. Specific Arguments Applicable to Individual Claims.

A. Plaintiffs' Negligence Claim (Count One) must be dismissed as Plaintiffs have failed to establish any duty owed by Medtronic.

Plaintiffs have completely failed to properly plead their claim that Medtronic was negligent with regard to the Devices.[11] In Minnesota, and every other state, in order to survive a motion to dismiss a negligence claim, plaintiff must allege: (1) defendant's "duty to the plaintiff; (2) a breach of that duty;

[11] Plaintiffs couch their allegations in terms of negligent manufacturing in an obvious attempt to avoid the preemption bar of negligent design claims. Plaintiffs' distorted allegations, however, cannot belie the truth that what they complain of is a negligent design issue. *See Id.* at ¶¶ 103-10.

(3) that the breach is the proximate cause of the plaintiff's injuries; and (4) that the plaintiff did in fact suffer an injury." *Boitz v. Preblich*, 405 N.W. 2d 907, 912 (Minn. Ct. App. 1987). Here, Plaintiffs failed to allege these four necessary elements.

Plaintiffs never allege Medtronic owed Plaintiffs a duty (first element). Rather, they only allege Medtronic's manufacturing processes "did not satisfy the Food and Drug Administration's Pre-Market Approval standards for the devices." Master Complaint at ¶ 105(a). Under Minnesota law, a plaintiff "must first *identify* and allege that the [defendant] owed and breached a *personal* duty . . . ." *Wicken v. Morris*, 527 N.W. 2d 95, 98 (Minn. 1995) (granting motion to dismiss because plaintiff did not properly allege existence of defendant's duty to plaintiff).

Plaintiffs fail to "identify" what duty Medtronic owed them: A duty to design and manufacture a device free of all potential problems and with guarantees that exceed FDA requirements? A duty to design and manufacture an ICD that never needs replacement? Having failed to identify a duty owed by Medtronic, it is not surprising that Plaintiffs failed to allege a "breach" of some unidentified duty (second element). Medtronic cannot be liable to Plaintiffs for breaching an invented duty -- as Judge Cardozo stated nearly a century ago, "negligence in the air" is not a recognized cause of action in any jurisdiction. *Palsgraf v. Long Island R. Co.*, 162 N.E. 99, 99 (N.Y. 1928) ("Proof of negligence in the air, so to

speak, will not do.") Simply put, and as a matter of law, Medtronic owes no duty to Plaintiffs different from or beyond what Medtronic owes the FDA.

More fundamentally, however, Plaintiffs have not alleged Medtronic's actions actually caused them injuries (third element), besides alleging mere potential personal injury, along with allegations of "economic loss" and "loss of companionship." *See* Master Complaint at ¶¶ 108-09. Because Plaintiffs cannot and do not specify actual injury due to Device malfunction (fourth element), their negligence claim fails regarding "economic loss" damages. In the vast majority of states, recovery for pure economic loss -- untied to actual physical injury resulting from device malfunction -- is unrecoverable under the economic loss doctrine. And because "loss of companionship" is derivative of the existence of an underlying tort, this cannot serve as Plaintiffs' injury.

As with their other claims, Plaintiffs' negligence claim fails because Plaintiffs do not allege actual injury from a Device malfunction. Without alleging this causal connection, Plaintiffs cannot base their injuries on pure economic loss or the derivative "damages" of their spouses. Count One must be dismissed under Rule 12(b)(6).

B. Plaintiffs' Negligence *Per Se* Claim (Count Three) must be dismissed because the Federal Food, Drug, and Cosmetic Act ("FDCA") expressly disallows private rights of action.

Before a plaintiff can argue that a statutory violation gives rise to negligence *per se* liability, plaintiff must first *be allowed* to sue under that statute.

In other words, the statute must authorize a private right of action. *See, e.g., In re Professional Financial Mgmt, Ltd.*, 692 F. Supp. 1057, 1065 (D. Minn. 1988) (disallowing a negligence *per se* claim because "[p]laintiffs have not shown the statute upon which they rely provides for a private right of action."); *Alumbaugh v. Union Pacific R. Co.*, 322 F. 3d 520, 524 (8th Cir. 2003) (refusing to allow negligence *per se* claim and stating: "For a negligence *per se* claim to succeed, it must be shown that the legislature intended to create a private right of action in favor of the class of persons to which the plaintiff belongs for violation of the statute").[12]

Here, Plaintiffs attempt to establish negligence *per se* under a statute that unquestionably denies them a private right of action. The FDCA expressly states all "proceedings for the enforcement, or to restrain violators, of this chapter *shall be by and in the name of the United States*." 21 U.S.C. § 337(a) (emphasis added). The Supreme Court endorsed this unambiguous congressional intent to disallow private actions, stating:

> The FDCA leaves no doubt that it is the federal government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions [of the Act].

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[12] Jurisdictions around the country follow this rule. *See* Restatement (Second) of Torts § 287 (noting that when a statute's enforcement provisions are "in lieu of all other remedies," that tort actions based on that statute -- under a negligence *per se* theory -- are "necessarily defeated").

Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341, 349 n.4 (2001).[13]

Thus, because Plaintiffs' negligence *per se* claim is based wholly upon a statute that precludes their right to sue, Count Three must be dismissed.

C. Plaintiffs' Warranty Claims (Counts Five and Six) should be dismissed, as Medtronic never had a contractual relationship with *any* Plaintiff.

1. "Promotional Statements" and "Product Literature" are not binding contracts.

An obvious and necessary element to a warranty claim is a contract between plaintiff and defendant. *See Kelso Farmers Mut. Fire Ins. Co. v. Massop Elec., Inc.*, 2000 WL 2607 *1 (Minn. App. 2001) ("To establish any breach of warranty claim, the plaintiff must prove (1) existence of a warranty; (2) a breach; and (3) proximate cause (a causal link between the breach and the alleged harm") (quoting *Peterson v. Bendix Home Sys., Inc.*, 318 N.W. 2d 50, 52-53 (Minn. 1982)).

Plaintiffs cannot allege a contract existed between Medtronic and themselves. In fact, the most they can allege is that "promotional statements" and "product literature" contained "express warrant[ies]" to Plaintiffs that apparently constitute valid and enforceable contracts. *See* Master Complaint at ¶ 136. Plaintiffs completely fail to describe (or attach) the contents of the "promotional statements" and "product literature" they claim form these contracts. As with

[13] A more detailed analysis of *Buckman* can be found in Medtronic's concurrently-filed Motion for Summary Judgment Regarding Federal Preemption.

virtually all states, Minnesota law,[14] however, provides that general advertisements cannot constitute binding contracts, especially where, as here, Medtronic did not advertise the Devices to Plaintiffs, but rather to hospitals and physicians. (Indeed, the Devices are not sold to patients, but rather primarily to hospitals). Not only do Plaintiffs fail to allege any proper basis for a contractual relationship between themselves and Medtronic, even if advertisements *could* constitute enforceable contracts, those contracts would be between Medtronic and the hospitals and physicians who actually bought the Devices -- not between Medtronic and Plaintiffs.

Because Plaintiffs cannot establish the existence of any valid contract, their warranty claims must be dismissed.

2. There can be no warranty claims without privity.

Under the majority of state laws at issue in this litigation, Plaintiffs' breach of warranty claims cannot survive dismissal. Medtronic cannot be liable to Plaintiffs for breaching a warranty Medtronic never made. Simply put, there is no privity between Medtronic and any individual Plaintiff. The Devices were sold directly to hospitals and physicians, who then "sold" the Devices to Plaintiffs.

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[14] For example, Minnesota courts hold "if goods are advertised for sale at a certain price, it is not an offer and no contract is formed; such an advertisement is merely an invitation to bargain rather than an offer." *See, e.g., Ford Motor Credit Co. v. Russell*, 518 N.W. 2d 460 (Minn. App. 1994) (quoting 1 Samuel Williston, *A Treatise on the Law of Contracts*, § 4:7 (4th ed. 1990).

This lack of contractual or "vertical" privity precludes Plaintiffs' breach of warranty claims. *See, e.g., T.W.M. v. American Medical Systems, Inc.*, 886 F. Supp. 842, 844 (N.D. Fla. 1995) (under Florida law, to recover for breach of warranty, either express or implied, "plaintiff must be in privity of contract with the defendant"); *see also Fieldstone Co. v. Briggs Plumbing Prods. Co.*, 54 Cal. App. 4th 357, 369 n.10 (1997) (noting "privity of contract is a required element of an express breach of warranty cause of action").

3. Even in states that do not require privity, Plaintiffs' warranty claims fail because their claimed personal injury damages are not recoverable under a breach of warranty theory.

While some states, such as Minnesota and South Carolina, have statutorily eliminated the need for privity in warranty claims, Plaintiffs' claims for personal injury damages still necessarily fail as a matter of law because Plaintiffs' claimed "injuries" (vaguely pled "personal injury" and "mental anguish") are not recoverable under a breach of warranty theory. *See, e.g.,* Minn. Stat. § 336.2-714(2) (1990) (noting the measure of damages for a seller's breach of warranty is "the difference between the value of goods at the time of delivery to the buyer and the value they would have had as warranted").

Plaintiffs are not asking for the difference in value between a Device with *no* possibility of battery failure (assuming such a device could be made) and a Device with a remote chance of exhibiting the battery shortening mechanism. The

injuries Plaintiffs *are* alleging are, therefore, outside the scope of the breach of warranty cause of action. Thus, even in states where the privity requirement has been relaxed, Plaintiffs' claims still fail.

4. Even if Plaintiffs have valid warranty claims, those claims only apply to Medtronic ICD's, and not CRT-Ds.

As with their fraud-based claims (Counts Seven through Eleven), Plaintiffs chose to include only ICDs and not CRT-Ds among the Devices giving rise to warranty claims against Medtronic. Thus, to the extent the Court finds Plaintiffs have warranty claims that withstand a motion to dismiss, only those Plaintiffs with implanted ICDs -- and not CRT-Ds -- should be able to pursue these claims.

D. In addition to being insufficiently vague, Plaintiffs' "Misrepresentation by Omission" Claim (Count Seven) substantively fails as a matter of law under the learned intermediary doctrine.

Plaintiffs' misrepresentation claim is barred substantively by the "learned intermediary" doctrine, as Medtronic had no duty to provide Plaintiffs with *any* warnings.

Plaintiffs allege Medtronic "withheld information pertaining to the inherent design and/or manufacturing defects," and that this was done "to induce the purchase of Defendant's ICD over other pacemaker/defibrillators on the market." *See* Master Complaint at ¶¶ 144-45. The learned intermediary doctrine, however, precludes this claimed liability. As adopted by numerous states, including Minnesota, the doctrine provides that a manufacturer of a prescription drug or

device has a duty to warn a physician of the risks associated with the use of the drug or device. The physician then acts as a "learned intermediary" between the manufacturer and patient. *See* Restatement (Third) of Torts § 6(d); *Ehlis v. Shire Richwood, Inc.*, 367 F.3d 1013, 1016 (8th Cir. 1994) ("[A] warning to the [physician] is deemed a warning to the patient; the manufacturer need not communicate directly with all ultimate users of the prescription drugs and devices").

Many states have adopted Minnesota's majority position of recognizing the learned intermediary doctrine. *See, e.g., Carlin v. Superior Court*, 13 Cal. 4th 1104, 1116-1118 (1996) (holding warnings concerning prescription drugs/medical devices are to be directed to the physician rather than the plaintiff); *Brooks v. Medtronic*, 750 F.2d 1227, 1230-32 (4th Cir. 1984) (holding a manufacturer's duty to warn extends only to the prescribing physician, who then assumes responsibility for advising the individual patient of risks associated with the drug or device).

Here, therefore, Medtronic cannot be liable for allegedly "concealing" information from Plaintiffs when Medtronic was under *no duty* to provide them information in the first place.

E. Plaintiffs' three claims under the Minnesota Fraud Statutes (Counts Eight through Ten) necessarily fail because (1) product liability claims by law do not "advance the public interest" and (2) these claims are barred by the "merchant exclusion."

1. Plaintiffs' product liability claims are not recognized as claims that "advance the public interest" -- a necessary element to assert a private cause of action under the Fraud Statutes.

The Minnesota Consumer Fraud statutes at issue[15] only allow for private causes of action in situations where those actions benefit the public. *See, e.g., Ly v. Nystrom*, 615 N.W. 2d 302, 308 (Minn. 2000). But when, as here, the essence of a plaintiff's action involves product liability allegations giving rise to personal injury damages, this "advancing the public interest" standard is not met. *See Berczyk v. Emerson Tool Co.*, 291 F. Supp. 2d 1004, 1020 (D. Minn. 2003) Claims that "seek damages for past and future medical expenses, pain and suffering, wage loss and emotional distress . . . do not benefit the public. The redress is to

[15] Plaintiffs base their claims upon Minn. Stat. § 325F.67 (Count Eight), § 325F.69 (Count Nine), and § 325D.44 (Count Ten). In addition to being inappropriate for the reasons advanced in this section, Plaintiffs' claims under this last statute – the Minnesota Deceptive Trade Practices Act (Count Ten) – should be dismissed because this Act does not allow for the monetary damages relief sought by Plaintiffs. *See* Master Complaint at ¶ 170 (noting how Plaintiffs' claims for "personal injuries, economic loss, [and others]" are "compensable injuries"); Minn. Stat. § 325D.45 Subd. 1 ("A person likely to be damaged by a deceptive trade practice of another may [only] be granted an *injunction* against it under the principles of equity . . . ."); *Simmons v. Modern Aero, Inc.*, 603 N.W. 2d 336, 339 (Minn. Ct. App. 1999) (holding that since "the [Act] provides only injunctive relief and because [plaintiff] pursued monetary damages, not an injunction, he has not stated a claim for which relief [can] be granted").

compensate Plaintiffs for their injuries." *Behrens v. United Vaccines Inc.*, 228 F. Supp. 2d 965, 971 (D. Minn. 2002).

Additionally, because the allegedly defective Devices at issue have been removed from the market, Plaintiffs cannot establish a "real prospect of a public benefit" from their consumer fraud claims. *See Behrens*, 228 F. Supp. 2d at 971 (explaining that even if the product was defective, "it could cause no harm to any other member of the public" after it was removed from the market). Nor can Plaintiffs argue that "but for" their action, Medtronic would continue to make false representations to the public's disadvantage. *See Tuttle*, 2003 WL 1571584 at *6 (rejecting plaintiff's contention that her lawsuit had a public benefit where marketing statements were made years earlier).

Likewise, any attempt by Plaintiffs to argue their claims may serve to deter future "false advertising" also fails. In rejecting this exact claim, the *Behrens* Court noted: "Undoubtedly, any successful lawsuit, which recovers damages for an injury caused by a defective product, could have the potential to cause some public benefit. However, such a broad application of the Private AG statute to affect the purposes of the Consumer Fraud Act was the precise type of misapplication that the Minnesota Supreme Court criticized in *Ly v. Nystrom*." *Behrens,* 228 F.Supp. 2d at 971.

Because the Devices are Class III medical devices subject to stringent FDA approval and oversight, the ability of any litigant to act as a private attorney general is federally circumscribed. When a private litigant acts in lieu of the Attorney General, "the scope of the Attorney General's roles and duties would properly define the scope of the private litigant's roles and duties." *Id.* at 969.

Because Plaintiffs' claims of statutory fraud, by law, cannot advance the "public interest," they should be dismissed.

2. Plaintiffs' claims under the Minnesota statutes are barred by the "merchant exclusion."

Plaintiffs' claims should also be dismissed because Minnesota's consumer protection statutes do not cover sales to "merchants" like the health care providers who bought Medtronic's Devices.

Under the "merchant exclusion," the sale of goods between merchants is not "an ordinary consumer transaction within the scope of state statutes regulating sales to consumers." *Church of the Nativity of Our Lord v. WatPro, Inc.*, 491 N.W.2d 1, 7 (Minn. 1992), *overruled on other grounds by Ly*, 615 N.W.2d at 314 n.25. [16] Thus, in *Solvay Pharms., Inc. v. Global Pharms.*, 298 F. Supp. 2d 880,

[16] A "merchant" is "a person who deals in goods of the kind or otherwise by his occupation holds out as having knowledge or skill peculiar to the practices or goods involved in the transaction or to whom such knowledge or skill may be attributed by employment of an agent or broker or other intermediary who by his occupation holds out as having such knowledge or skill." *WatPro, Inc.*, 491 N.W.2d at 7 (quoting the definition set forth in the Uniform Commercial Code).

886-87 (D. Minn. 2004), the district court held that the Minnesota Consumer Fraud Act ("MCFA") did not apply to a pharmaceutical manufacturer's sales to wholesalers, chains, distributors, mail order houses, independent pharmacies, and managed health care organizations, because those entities' "expertise in the pharmaceutical industry" brought them within the definition of "merchant."

As in *Solvay*, the health care providers to whom Medtronic sold Devices are merchants by virtue of their expertise in making medical determinations about the use of defibrillators with particular patients. These medical professionals, "by [their] occupation, hold out as having knowledge or skill peculiar to the . . . goods involved." *WatPro, Inc.*, 491 N.W.2d at 7. Medtronic's sales of defibrillators to health care providers were not "an ordinary consumer transaction within the scope of state statutes regulating sales to consumers." *Id*; *see also Gas Aggregation Svcs. v. Howard Avista Energy, LLC*, 319 F.3d 1060, 1069 (8th Cir. 2003) (holding that MCFA did not apply to transactions between sophisticated gas traders because such transactions "are not consumer transactions at all"); *Stephenson v. Deutsche Bank AG*, 282 F. Supp. 2d 1032, 1068 (D. Minn. 2003) (holding Minn. Stat. §§ 325F.68-70 did not apply to transactions between sophisticated securities broker-dealers and securities lenders).

Because these decisions were made by sophisticated health care providers, Plaintiffs' consumer protection claims are barred by the "merchant exclusion" and must be dismissed.

F. Plaintiffs' generally-pled consumer fraud claims of the other states (Count Eleven) fail to plead the elements of statutory fraud in each of the 50 states.

Plaintiffs assert their claims under the consumer protection laws of the various states in the following manner: "Defendants [sic] engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of the state consumer protection laws listed below . . . ." *See* Master Complaint at ¶ 173. Plaintiffs then request that this Court interpret and apply the consumer fraud statutes of all 50 states. *See id.*

While Plaintiffs claim a right to recover under all 50 consumer protection laws and the District of Columbia, they fail completely to allege facts suggesting they are constitutionally entitled to bring a claim against Medtronic under the laws of *any* state besides Minnesota. Plaintiffs have alleged no significant contacts or aggregation of contacts between their claims and the laws of New York, Florida, Texas, California, or any of the other fifty jurisdictions besides Minnesota. This defect alone mandates dismissal of Plaintiffs' consumer fraud claims. *See* Master Complaint ¶¶ 175-221.

Plaintiffs also fail to allege the proper *elements* of each and every statute. This also provides the basis for dismissal of Plaintiffs' consumer-fraud claims: As

one MDL court noted when it dismissed a similarly poorly pled consumer fraud claim, "Each state's [consumer protection] statute is unique and plaintiffs are *required to plead the essential elements of each one*. Plaintiffs have completely failed to do so." *In re Gen. Motors Corp. Anti-Lock Brake Prods. Liab. Litig.*, 966 F. Supp. 1525, 1536 (E.D. Mo. 1997). Thus, because Plaintiffs have failed to plead the "essential elements" of *each* of their consumer fraud claims, these claims must be dismissed.

The reason courts require plaintiffs to specifically plead the elements of consumer protection claims is simple: The elements of consumer protection laws vary greatly. *Compare* Cal. Bus. & Prof. Code § 17500 (defining "unfair competition" as "dissemination of any statement . . . which is known . . . or *should be known* to be untrue or misleading") with Nev. Rev. Stat. Ann. § 598.0903 (2003) (requiring defendant "knowingly made a false representation in a transaction"). Thus, while some states require a defendant knew a statement was misleading, others only require that a defendant *should* have known. Still others have *no* scienter element. Some statutes go further and require intent, with regard to "concealments," but no intent to deceive, with regard to "misrepresentations." N.J. Stat. Ann. § 56:8:1.[17]

[17] Various states' consumer protection laws diverge wildly on numerous fronts besides the "scienter" or "level of intent" element. For example, with regard to standing requirements, some statutes limit standing to competitors. *See* DEL.

Here, because Plaintiffs have not alleged the elements necessary to maintain statutory fraud claims under *each* of the 50 states, Count Eleven must be dismissed.

VI. Conclusion.

For the foregoing reasons, Medtronic respectfully requests that the Court grant its Motion and dismiss Plaintiffs' Master Complaint in its entirety.

Respectfully submitted,

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CODE ANN. TIT. 6 § 2533 (unless action brought by Attorney General on behalf of consumers); OKLA. STAT. ANN. TIT. 78, § 53. Others can only be enforced by the Attorney General. *See* IOWA CODE § 714.16 (4)-(7); NORTH DAKOTA STAT. § 51-15-02. Some states do not permit individual plaintiffs to bring class actions. *See* ALA. CODE § 8-19-10(f); GA. CODE § 10-1-399(a); MISS. CODE ANN. § 75-24-15(4); MONT. CODE ANN. § 30-14-133; OHIO REV. CODE ANN. § 1345.09(B). Some states permit a private cause of action only where an administrative order has been violated. *See* WIS. STAT. § 100.20(5). Other states prohibit private actions for damages. *See* GA. CODE ANN. § 10-1-373; HAW. REV. STAT. ANN. § 481A-4; ME. REV. STAT. ANN., Tit. 10, § 1213 (injunction only remedy under Act). Several states require a plaintiff to provide written notice of their claims before filing a lawsuit. *See* CAL. CIV. CODE § 1782; TEX. BUS. & COM. CODE ANN. § 17.505. Several other states prohibit a private cause of action unless the alleged unfair or deceptive act impacts the public interest. *See Ly v. Nystrom*, 615 N.W.2d 302, 314 (Minn. 2000); *Hall v. Walter*, 969 P.2d 224 (Colo. 1998); *Bauer v. Mellon Mortgage Co.*, 680 N.Y.S.2d 397, 400 (N.Y. Sup. Ct. 1998).

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